UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

In re DR. REDDY'S LABORATORY LIMITED SECURITIES LITIGATION	Civil Action No. 3:17-cv-6436 (PGS) (DEA)
	MEMORANDUM AND ORDER

SHERIDAN, U.S.D.J.

Defendant Dr. Reddy's Laboratories, Ltd. (Dr. Reddy's), Dr. Reddy's Laboratories Inc. (Dr. Reddy's USA), Abhijit Mukherjee, Satish Reddy, Saumen Chakraborty, and G. V. Prasad (collectively, Defendants), bring this motion to dismiss Plaintiff's Amended Consolidated Class Action Complaint ("Amended Complaint" or "AC") in its entirety for lack of standing and failure to state a claim. (ECF No. 47).

The allegations in this complaint arise under 15 U.S.C. § 78j(b), 78t(a), and 17 C.F.R. § 240.10b-5. Therefore, this Court has jurisdiction pursuant to 15 U.S.C. § 78aa and 28 U.S.C. § 1331. On May 9, 2018, Defendant filed this motion to dismiss the Amended Complaint. (ECF No. 47).

BACKGROUND

The Public Employees' Retirement System of Mississippi provides retirement benefits to Mississippi public employees, and manages approximately $27.1 billion on behalf of beneficiaries. The Amended Complaint alleges Plaintiff purchased securities "at artificially inflated prices during the Class Period and was damaged upon revelation of the alleged corrective disclosures." (AC at

¶ 53). Plaintiff purchased Dr. Reddy's securities between March 30, 2016 and April 6, 2016. (Declaration of Joel B. Strauss in Support of the Motion to Appoint Lead Plaintiff (Strauss Decl.), ECF No. 12, Ex. A, Certification of Jacqueline H. Ray, Ex. A, Mississippi PERS' Transactions in Dr. Reddy's Securities). However, the Amended Complaint defines the class period as November 27, 2014 through September 15, 2017. (AC at p. 1).

Defendant Dr. Reddy's is an Indian pharmaceutical manufacturing company with a United States headquarters in New Jersey. (AC at ¶ 54). Dr. Reddy's securities are traded on the New York Stock Exchange. (*Id.*). Defendant Dr. Reddy's, USA, is a wholly owned United States subsidiary of Dr. Reddy's that "is primarily engaged in developing, manufacturing, and marketing generic pharmaceuticals and [active pharmaceutical ingredients] in the United States." (*Id.* at ¶ 55).

Defendant G.V. Prasad was the Chief Executive Officer and co-chairman of Dr. Reddy's during the class period. (*Id.* at ¶ 56). Defendant Saumen Chakraborty was the Chief Financial Officer and President of Dr. Reddy's during the class period. (*Id.* at ¶ 58). Defendant Abhijit Mukherjee was the Chief Operating Officer of Dr. Reddy's during the class period. (*Id.* at ¶ 60). Satish Reddy was co-chairman of Dr. Reddy's during the class period. (*Id.* at ¶ 62). All of the individual Defendants are alleged to have had "actual power and influence over Dr. Reddy's and the statements made by Dr. Reddy's." (*Id.* at ¶ 53, 55, 57, 59).

Dr. Reddy's allegedly misrepresented that it met mandatory manufacturing quality standards when it did not. This misdeed was in violation of the U.S. Federal Food, Drug and Cosmetic Act (FD&C Act) which prohibits the import of "adulterated" drugs. *See* 21 U.S.C. § 331(a); (AC at ¶ 1). Plaintiff asserts that Defendants are subject to current good manufacturing practices (cGMP) which sets minimum standards for safely manufacturing drugs by outlining

general rules for all aspects of drug manufacture including facilities, personnel, equipment, drug components and containers, production, packaging, labeling, and record keeping. (AC at ¶ 2). Dr. Reddy's compliance with cGMP came into question after investors learned that the FDA observed nine potential violations at Dr. Reddy's manufacturing facility Unit VI, one of the largest facilities, in November 2014. (*Id.* ¶ 3). Dr. Reddy's and other corporate executives falsely assuaged the market's fears and downplayed the potential impact on manufacturing by stating in the June 17, 2015 annual report that "[a]ll of the [Dr. Reddy's] facilities are designed in accordance with and are compliant with current Good Manufacturing Practice requirements." (*Id.*).

According to Plaintiff, the fraud began to unravel in November 2015 when the Food and Drug Administration (FDA) publicly issued a Warning Letter (the "Warning Letter") that described three of Dr. Reddy's manufacturing facilities as suffering from "recurrent" and "long-standing failures," with some violations dating back to 2008. (*Id.* at ¶ 4). The Warning Letter questioned Dr. Reddy's ability "to achieve overall compliance with CGMP" and concluded, "It is apparent that [Defendants] have not implemented a robust quality system at [Dr. Reddy's] sites." (*Id.* at Exhibit 5). The FDA "strongly recommend[ed]" that Defendants "evaluate global manufacturing operations to ensure compliance with CGMP regulations and requirements, comprehensively and immediately." (*Id.* ¶ 4).

Following the receipt of the November 2015 Warning Letter, Defendants allegedly continued to fraudulently downplay the impact of their purported compliance-related efforts on ongoing manufacturing. (*Id.* at ¶ 5). In February and July 2016, Defendants disclosed that production had been slowed as a result of the remediation. (*Id.*). In an October 25, 2016 earnings call, Defendants also touted that they had "done [their] part of it in terms of completing all the remediation activities." (*Id.* at ¶ 263).

However, between February 27 and March 8, 2017, the FDA re-inspected the three facilities under the Warning Letter and again found problems at all three facilities. (*Id.* at ¶ 6). One facility – Unit VII – was particularly problematic; the FDA's internal Establishment Inspection Report regarding the early 2017 inspection "found that numerous items had not been corrected" and during the inspection "repeated instances of employees providing false or misleading statements [were] discussed with firm management." (*Id.* at ¶¶ 6, 321).

During the summer of 2017, a string of disclosures revealed just how little Dr. Reddy's had accomplished in its purportedly "network wide" remediation. (*Id.* at ¶ 7). In August 2017, the German equivalent of the FDA rescinded Dr. Reddy's compliance certificate for a whole new facility, Unit II, which had not been implicated by the Warning Letter. (*Id.*). Similarly, in September 2017, the FDA found more observations of potential non-compliance at a facility based in the United Kingdom. As a result of these disclosures, the price of Defendants' U.S.-traded securities dropped over 50% from their pre-Warning Letter class period high. (*Id.*).

Plaintiff alleges that investors were damaged by Defendants' materially false and misleading statements throughout the class period concerning: (i) Dr. Reddy's compliance with manufacturing quality regulations, including cGMP; (ii) the scope and severity of the FDA's observations of non-compliance; (iii) the company's purported progress getting back into compliance; and (iv) the extent to which getting back into compliance would impact ongoing production. (*Id.* at ¶ 8).

Dr. Reddy's, like all pharmaceutical manufacturers, has a non-delegable duty to ensure that the drugs and pharmaceutical ingredients it produces are safe, effective, and in compliance with the regulations in the jurisdictions in which they are sold. (*Id.* at ¶ 9). For drugs sold in the United States, the regulatory regime is premised on the cGMP, which are promulgated by the FDA and

codified in the Code of Federal Regulations (21 C.F.R. Parts 210 and 211). (*Id.* at ¶ 9). Plaintiff alleges that Dr. Reddy's routinely violated fundamental precepts of the cGMP. (*Id.* at ¶ 10). For example, when errors or discrepancies in the manufacture of a drug are discovered during the quality control testing phase – such as the accidental production of a batch of super- or sub-potent drugs – the manufacturer must "thoroughly" investigate and identify the cause of the error. (*Id.*); *See* 21 C.F.R. § 211.192. The FDA allegedly found numerous instances where Dr. Reddy's management knew about deviations and errors in the production of drugs at three of its largest and most important facilities yet took no action to investigate the cause of the error or to correct it. (*Id.*).

Starting in 2012 through the start of the class period, Dr. Reddy's management oversaw a dramatic increase in the volume of production at the company's manufacturing facilities, including those at the center of this action. (*Id.* ¶ 12). However, a well-placed confidential witness and former Dr. Reddy's employee, identified as "CW 1," who had firsthand information of Dr. Reddy's manufacturing facilities in India, stated that the ramp up in production output led to increased quality problems and delays. (*Id.*). As a result, significant pressure was put on the quality teams to cut corners and release batches of products from the review cycle without performing adequate quality assurance or control. (*Id.*).

In November 2014, after performing an unannounced on-site inspection of Unit VI, one of Dr. Reddy's largest manufacturing facilities, the FDA caught Dr. Reddy's shirking on its responsibility to follow the cGMP and other mandatory regulations used to ensure drug safety. (*Id.* at ¶ 13). They communicated that they observed nine objectionable instances of potential non-compliance. (*Id.*). For example, Dr. Reddy's allegedly had manipulated and deleted quality control testing data using a quality control laboratory that was not disclosed to the FDA. (*Id.*). Dr. Reddy's

had used the undisclosed lab to test and retest batches of pharmaceutical products that had failed quality control until they successfully passed muster. (*Id.*). The FDA privately communicated these observations to Defendants in a November 21, 2014 FDA Form 483 Notices of Inspectional Observations. (*Id.* at ¶¶ 13, 120).

At the start of the class period, on November 27, 2014, investors learned of the FDA's observations of potential non-compliance at Unit VI from an online industry publication named In-Pharmatechnologist.com and an Indian publication named the Deccan Chronicle. (*Id.* at ¶¶ 14, 214, 224). Nevertheless, that same day, Defendants immediately issued a press release "clarification" and commented in the industry publication. (*Id.* at ¶¶ 14, 158, 214). They acknowledged receipt of the FDA Form 483, but then inaccurately assuaged investors' fears, claiming "there is no implication on manufacturing," and that they were "confident it [wouldn't] lead to any further enforcement." (*Id.* at ¶¶ 14, 158, 214).

Analysts covering Dr. Reddy's apparently did not believe the FDA Form 483 would adversely affect the company. (*Id.* at ¶¶ 15, 221). The next day, November 28, 2014, an analyst named IndiaNevish issued a report stating: "[Dr. Reddy's] has clarified that these observation[s] would not have any material impact on company's operation or consolidated results . . . . We find non-stoppage of production from facility under observation to be positive for [Dr. Reddy's] as it implies [Dr. Reddy's] following norms to comply with USFDA regulation." (*Id.* ¶¶ 15, 221). The report was available on publications including Bloomberg INNS, Thomson First Call, Reuters, and Factiva INDIV. (*Id.* at ¶ 221 n.6).

Dr. Reddy's went on to privately receive at least two more FDA Form 483s for two other manufacturing facilities in India in January and March 2015. (*Id.* at ¶ 16). Together, the thirty-three observations at three different facilities depicted a pervasive pattern of: (1) neither recording

nor maintaining quality control testing data; (2) failing to investigate the cause of failing quality control test results; and (3) failing to mitigate the risks of microbiological contamination. (*Id.*).

Despite receiving these two additional FDA Form 483s, Defendants allegedly knowingly misled investors by claiming that they were in full compliance with cGMP. (*Id.* at ¶ 17). For example, on June 17, 2015, Defendants claimed in their annual report for the year ended March 31, 2015, that "[a]ll of the facilities are designed in accordance with and are compliant with" the cGMP. (*Id.*).

Further, on July 30, 2015, Defendants falsely claimed that their compliance issues were "pretty much a one site specific issue" and that they had "comprehensively addressed almost all the observations raised" despite having received two additional FDA Form 483s for two separate facilities and, according to the FDA, having proposed woefully inadequate corrective actions. (*Id.* at ¶ 18 (emphasis omitted)).

Plaintiff contends that Defendants failed to fix the problems at their manufacturing facilities – despite claiming they had – and the FDA escalated its enforcement by issuing the November 2015 Warning Letter to Defendant Reddy. (*Id.* at ¶ 19). The Warning Letter had revealed that Dr. Reddy's manufacturing quality problems were not an isolated "one site specific issue," but rather, a pattern of cross-facility, persistent violations. Multiple violations dating back to 2008 and multiple observations from the FDA Form 483s remained uncorrected. (*Id.*; *see* AC at Exhibits 2 (March 6, 2015 Form 283), 3 (January 31, 2015 Form 283), 4 (November 21, 2014 Form 483), 5 (November 2015 Warning Letter)).

Furthermore, the Warning Letter memorialized portions of Defendants' responses to the FDA following their receipt of the three FDA Form 483s. (AC at ¶ 20). The FDA's descriptions

of these responses show that Defendants knew about the specific non-compliant conditions at the same time they claimed that all manufacturing facilities were "compliant" with the cGMP. (*Id.*).

For instance, in a December 15, 2014 letter responding to the FDA Form 483 issued to Unit VI in November 2014, Defendants attempted to justify their use of an undisclosed quality control lab to test and retest products until they passed, while only recording passing results. (*Id.* at ¶ 21). According to the FDA, Defendants' response "acknowledged that [their] analysts failed to document and start investigating [out-of-specification] results" in the undisclosed quality control lab. (*Id.*). However, the November 2015 Warning Letter concluded that eleven months after the December 2014 letter, Defendants still had "not assessed how [their] reliance on the incomplete and inaccurate data generated by the [custom quality control] laboratory" affected the quality of the facility's products. (*Id.*) Defendants' late 2014 and early 2015 acknowledgments in their responses to the FDA establish their knowledge that the statements were false and misleading. (*Id.*).

Based on these observations and others, the Warning Letter concluded: "Several violations are recurrent or represent long-standing failures to adequately resolve significant manufacturing quality problems. It is apparent that you have not implemented a robust quality system at your sites." (*Id.* at ¶ 22, Ex. 5, Warning Letter at 9).

Wall Street analysts covering Dr. Reddy's were surprised by the Warning Letter. A Morgan Stanley analyst stated, "Hitherto, only one site, which is located at Srikakulam [(Unit VI)] was perceived to be under FDA risk; warning letters to two additional sites is disappointing." (*Id.* at ¶ 21). Equirus echoed the surprise: "While we knew about the Srikakulam facility issues, we never knew about the seriousness of observations at the other plants – mainly as management

commentary was very optimistic in the quarterly calls. This clearly is significantly against our expectations . . . ." (*Id.* at ¶ 23).

On November 6, 2015, Dr. Reddy's issued a press release publicly acknowledging that it had received the Warning Letter, marking the first time the market learned of same. (*Id.* at ¶¶ 198, 248, 291). Dr. Reddy's American Depositary Shares ("ADSs") dropped 18%. (*Id.* at ¶ 24). When reports in the media first circulated on November 27, 2015, Dr. Reddy's ADSs dropped an additional 5.6%. (*Id.* at ¶ 24).

Nevertheless, instead of acknowledging the significant impact that an "organization-wide" "revamp [of their] quality systems and processes" to "fully comply with the cGMP quality standards across all of [their] facilities" would have on production, Defendants claimed on November 9, 2015 that they had "de-risked" the three facilities subject to the Warning Letter and there would be minimal impact on manufacturing. (*Id.* at ¶ 25). As part of the remediation, Defendants promised to engage an outside consultant to perform a "third party assessment of [their] quality systems and evaluate [their] global manufacturing operations to ensure compliance with CGMP regulations" as required by the FDA. (*Id.* at ¶ 26).

On November 5, 2015, Defendants hired Lachman Consultants Services, Inc. ("Lachman"), a consulting firm that specializes in responding to FDA warning letters. (*Id.* at ¶¶ 26, 61). According to CW 1, Lachman came in after Dr. Reddy's received the Warning Letter; due to Dr. Reddy's extended review process and Lachman's subsequent review, Dr. Reddy's batch releases slowed down by as much as 66%, and management was fully aware of this slow down. (*Id.* ¶ 27).

Just three months after receiving the Warning Letter, on February 9, 2016, Defendants had to admit, contrary to their earlier public statements, that Dr. Reddy's was indeed experiencing

manufacturing delays due to the remediation, causing the price of Dr. Reddy's ADSs to drop almost 6%. (*Id.* at ¶ 28).

Defendants then falsely claimed these delays were essentially a one-time occurrence and manufacturing was "back on track." (*Id.* at ¶ 29). However, on July 26, 2016, Dr. Reddy's revealed that the company's remediation efforts had once again substantially delayed production at the impacted facilities. (*Id.*). As a result of this news on July 26, 2016, the price of Dr. Reddy's ADSs dropped an additional 15%. (*Id.*).

Plaintiff alleges that in addition to misleading the market about production delays caused by the remediation, Defendants misled the market about their progress in remediating the company's non-compliance. (*Id.* at ¶ 30). On May 12, 2016, Defendants claimed that they believed that "most of [their] commitments to the [FDA] will be over by the end of [May 2016]." (*Id.*). Similarly, Defendants claimed on July 26, 2016, that they had completed up to 98% of their commitments to the FDA. (*Id.*). However, at the time of these statements, Defendants knew they had not corrected the problems at the three facilities under the Warning Letter, nor had they completed a network wide revamp of the company's compliance processes. (*Id.*).

On March 8, 2017, the market further learned the true state of Dr. Reddy's purported "system wide" remediation efforts when news broke that Dr. Reddy's had failed the FDA's re-inspection of Unit VII, receiving thirteen FDA observations in a March 8, 2017 Form 483. (*Id.* at ¶ 31; Exhibit 7). This news revealed the falsity of Defendants' claims that, since July 2016, they had basically addressed all of the FDA concerns and were merely awaiting re-inspection. (*Id.* at ¶ 31). Based on the news, the price of Dr. Reddy's ADSs fell once again, this time by more than 5% over two days. (*Id.*).

Thirteen days later, on March 21, 2017, additional information about the failed re-inspection came to light following an economic news channel's report that "US FDA finds repeat observations from 2015 warning letter. Failed to maintain complete data to ensure compliance." (*Id.* at ¶ 35). The news of five repeat observations from the Warning Letter continued to reveal the falsity of Defendants' claims that they had fully addressed the FDA's concerns. (*Id.* at ¶ 32).

Additionally, the subsequently-released Unit VII establishment inspection report, dated April 4, 2017, which accompanied the Form 483, made clear that management knowingly took no action concerning, among other things, more than 1,200 documentation errors from May 2016 to October 2016 in violation of cGMP. (*Id.* at ¶ 32; Exhibit 9). Consequently, the price of Dr. Reddy's ADSs took another hit, falling more than 6%. (*Id.* at ¶ 32).

Finally, a string of disclosures during the summer of 2017 fully revealed just how little Dr. Reddy's had accomplished in its purportedly "network wide" remediation. (*Id.* at ¶ 33). On August 10, 2017, the company revealed that a German regulator would not renew a cGMP compliance certificate for a manufacturing facility that was entirely separate from the facilities under the Warning Letter. (*Id.*). After investors learned about the revocation of a compliance certificate at the new facility, the price of Dr. Reddy's ADSs fell almost 6% from its previous close. (*Id.*). Similarly, on September 15, 2017, Dr. Reddy's disclosed that the company had been advised of new FDA observations of potential non-compliance at a United Kingdom manufacturing facility. (*Id.*).

When the truth was fully and finally revealed on September 15, 2017, the value of Dr. Reddy's ADSs had dropped to $33.78 from its class period high of $65.25 just before the issuance of the November 2015 Warning Letter. (*Id.* at ¶¶ 34, 297). From its class period high just before

the issuance of the Warning Letter, Dr. Reddy's ADSs had fallen a staggering 50.17% in value. (*Id.*).

Overall, Plaintiff has set forth twenty-two individual misstatements upon which the complaint is based:

- Misstatement 1: In an online publication named In-Pharmatechnologist.com dated November 27, 2014, a Dr. Reddy's spokesperson commented that the Form 483 observations by the FDA "were largely related to procedural and other compliances of the plant system"; "there is no implication on manufacturing and at this stage production continues as normal." The spokesperson also stated she was "confident that it [wouldn't] lead to any further enforcement." (AC at ¶ 214-15 (emphasis omitted)).
- Misstatement 2: Dr. Reddy's posted a clarification on November 27, 2014, on the Bombay Stock Exchange website clarifying a news article, which stated:

> The Company clarified stating that the company had received some inspectional observations from the US FDA after their visit to their API manufacturing facility in Srikakulam district of Andhra Pradesh. The company is committed to respond to the agency within stipulated timelines with their remedial plans and start implementing the necessary measures immediately. At this stage, it has no implication on any activity at the plant. Hence, these are not expected to be material to the Company[']s operations or consolidated results.

  (AC at ¶ 216 (emphasis omitted)).
- Misstatement 3: During a January 29, 2015 earnings call to address "Q3 FY 2015," Defendant Mukherjee engaged in the following conversation:

> Analyst: A quick question on Srikakulam [(Unit VI)]. My understanding has been that over the last few years, FDA generally does not stop product approvals with the 483s. It requires a warning letter, so why is that for you FDA has taken that stance?

> Abhijit Mukherjee: . . . [I]f your question is a direct question that whether we will be [getting a] warning letter, I do not know. That is not our expectation. We have responded comprehensively to the nine observations [regarding Srikakulum]. We are sending an update as we speak and let us see how that pans out.
>
> . . . .
>
> Analyst: So just a personal thought and since it is very important for everyone, so therefore I am just pressing on that. Sir observations such as readings falling out of specifications being recorded as falling within the specifications, does it not really border on the lines of data integrated issues, what is really our internal assessment on observations such as these?
>
> Abhijit Mukherjee: So what is available and you read are the observation by FDA. What you do not have access to are the rationale and the reasoning and the answers on this. So what I am telling you is that we have answered fairly comprehensively on most of these. Are not there insights and learning? - Yes there are insights and learning but we have answered fairly comprehensively to more of the observations. Per se if you read the observations it does not give you the full story.

(AC at ¶ 225 (emphases omitted)).

- Misstatement 4: During a July 30, 2015 earnings call to address "Q1 FY 2016," Defendant Mukherjee engaged in this exchange:

> Analyst: So per se, the 483 issue does not like really stop you from getting on the other ANDAs, right?
>
> Mukherjee: By no means. This is pretty must one site specific issue. A huge amount of organizational effort is standing for us everywhere where we are. Taking this is a drive to see how else we could more train, more do IT backup.

(AC at ¶ 228 (emphasis omitted)).

- Misstatement 5: On December 26, 2014, Defendants posted a clarification on the Bombay Stock Exchange in response to a report that Canada had placed an import restriction on the Unit VI facility. It stated:

> The Exchange had sought clarification from Dr. Reddy's Laboratories Ltd. with respect to news article appearing in Asian Age on December 26, 2014, titled "DRL under health Canada Scanner."
>
> . . . Our products continue to meet intended quality standards, and we believe that, our APIs and Finished drug products manufactured using these APIs pose no risk to the health and safety of the Canadian people. The Company is working with the agency for a satisfactory resolution of the matter. At this stage, it has no implication on any activity at the plant and hence, these are not expected to be material to the Company's operation or consolidated results.

(AC at ¶ 230 (emphases omitted)).

- Misstatement 6: In Dr. Reddy's May 12, 2015 Annual Report for 2014-2015, Defendants stated that their "focus on innovation-led affordability gives our customers access to the most complex active ingredients, while maintaining a consistent global quality standard."

(AC at ¶ 231 (emphasis omitted)).

- Misstatement 7: On June 17, 2015, Defendants filed their Form 20-F for the year ending March 31, 2015; it stated:

> Quality. We are fully dedicated to quality and have robust quality processes and systems in place at our developmental and manufacturing facilities to ensure that every product is safe and of high quality. In addition, we have integrated "Quality by Design" to build quality into all processes and use quality tools to minimize process risks.

(AC at ¶ 232 (emphasis omitted)).

- Misstatement 8: That same Form 20-F also provided:

> Manufacturing for our Global Generics segment entails converting active pharmaceutical ingredients ("API") into finished dosages. As of March 31, 2015, we had thirteen manufacturing facilities within this segment. Eleven of these facilities are located in India and two are located in the United States (Shreveport, Louisiana; and Bristol, Tennessee). In addition, we also have one packaging facility in the United Kingdom. All of the facilities are designed in accordance with and are compliant with current Good Manufacturing Practice ("cGMP") requirements and are used for the manufacture of tablets, hard gelatin capsules, injections, liquids and creams for sale in India as well as other markets. All of our manufacturing sites' laboratories and facilities are designed and maintained to meet increasingly stringent requirements of safety and quality.

(AC at ¶ 233 (emphases omitted)).

- Misstatement 9: On June 23, 2016, Defendants filed their Form 20-F for the year ending March 31, 2016; it stated:

> Quality. We are fully dedicated to quality and have robust quality processes and systems in place at our developmental and manufacturing facilities to ensure that every product is safe and of high quality. In addition, we have integrated "Quality by Design" to build quality into all processes and use quality tools to minimize process risks.

(AC at ¶ 238 (emphasis omitted)).

- Misstatement 10: That same Form 20-F also provided:

> Manufacturing for our Global Generics segment entails converting active pharmaceutical ingredients ("API") into finished dosages. As of March 31, 2016, we had thirteen manufacturing facilities within this segment. Eleven of these facilities are located in India and two are located in the United States (Shreveport, Louisiana; and Bristol, Tennessee). In addition, we also have one packaging facility in the United Kingdom. All of the facilities are designed in accordance with and are compliant with current Good Manufacturing Practice ("cGMP") requirements and are used for the manufacture of tablets, hard gelatin capsules, injections, liquids and creams for sale in India as well as other markets. All of our manufacturing sites' laboratories and facilities are designed and maintained to meet

> increasingly stringent requirements of safety and quality. All of our sites outside of India are approved by the respective regulatory bodies in the jurisdictions where they are located.

(AC at ¶ 239 (emphases omitted)).

- Misstatement 11: Misstatement 11 refers to multiple statements on Dr. Reddy's website, which are relevant because on May 12, 2015, Defendants issued their annual report for the year 2014-2015, which stated that the "primary source of information regarding the operations of the Company is the corporate website: www.drreddys.com." Those statements appeared on the corporate website in or around July 2016:

  - "Dr. Reddy's custom manufacturing operates in India, Mexico and the UK. These facilities have been built and are operated in accordance with the latest cGMP regulatory guidelines. Health and safety compliance is of the highest priority."

  - "Our expertise in intellectual property and regulatory issues helps us consistently deliver the highest quality APIs that meet or exceed regulatory standards."

  - "CPS' API manufacturing operates across nine cGMP facilities: seven in India; one in Mexico; and one in the UK. These facilities have been built and are operated in accordance with the latest cGMP regulatory guidelines. All of our facilities have been inspected by the USFDA and numerous other international regulatory agencies for all major products. Health and safety compliance is of the highest priority across all aspects of CPS, including plant installation, equipment, systems, and trained personnel."

  (AC at ¶¶ 240-43 (emphases omitted)).

- Misstatement 12: In a June 12, 2016 annual report for 2015-2016 signed by Defendant Reddy, Dr. Reddy's stated that "focus on innovation-led affordability gives our

customers access to the most complex active ingredients, while maintaining a consistent global quality standard." (AC at ¶ 244 (emphasis omitted)).

- Misstatement 13: In a November 6, 2015 press release, Defendant Prasad stated: "We take quality and compliance matters seriously and stand by our commitment to fully comply with the cGMP quality standards across all of our facilities," and also stated that Defendants "embarked on an initiative to revamp our quality systems and processes, as an organization-wide priority." (AC at ¶ 248 (emphases omitted)).
- Misstatement 14: In a November 9, 2015 conference call concerning the Warning Letter, Defendant Prasad commented:

> [W]e plan to do a comprehensive assessment of any risk to the quality of our products. . . . This recent letter underscores the need for us to re-evaluate the work done in light of the observations received, and continue to implement the CAPAs fully, assist the impact of FDA's observation on our products as well as enhance our overall quality management system. We'd also need to perform additional detailed third party assessment of our quality systems and evaluate our global manufacturing operations to ensure compliance with CGMP regulations.

(AC at ¶ 249 (emphasis omitted)). He also stated, "We have embarked on an initiative to revamp our quality systems and processes as a top organizational priority" and that Dr. Reddy's would "not compromise on making any required investments in terms of investments, training, consultancy as well as other areas as may be required to bring us back into compliance." (AC at ¶ 250 (emphases omitted)).

- Misstatement 15: In a February 9, 2016 earnings call concerning "Q3 FY 2016," Defendant Mukherjee stated:

> . . . Post receipt of the warning letter from US FDA in early November 2015 for three of our sites, we submitted on December 7, 2015, a comprehensive, corrective and

> preventive action plan, which in short is called CAPA to address all the issues raised. The CAPA plan includes site-specific CAPA, manufacturing network-wide CAPA and CAPA to sustain and enhance our quality and compliance performance on an ongoing basis. As of January 31, 2016, all the CAPA which were due for completion have been completed.
>
> We have submitted a status update to the warning letter response on January 28, 2016, stating our progress on accelerated remediation efforts towards sustainable compliance. As part of this quality journey, we have engaged well-respected third-party consultants, US-based Lachman [C]onsultants to provide necessary compliance and remediation support for assuring robust implementation and verification of the CAPA plan.

(AC at ¶ 251 (emphases omitted)).

- Misstatement 16: In a May 12, 2016 earnings call concerning "Q4 FY 2016," Defendant Mukherjee stated:

> [W]e submitted our first update to the FDA on January 28, followed by a second update on March 30th this year, stating our progress toward sustainable compliance. We believe most of our commitments to the agency will be over by the end of this quarter and post which we will request the agency for re-inspection.

(AC at ¶ 257 (emphases omitted)).

- Misstatement 17: During a July 26, 2016 earnings call concerning Q1 FY 2017, Defendants Mukherjee and Chakraborty made multiple statements:
  - Mukherjee: Defendants "have completed most of the commitments." (AC at ¶ 258 (emphasis omitted)).
  - Chakraborty: Remediation measures' completion is "[v]ery high, closer to 97%, 98%. (AC at ¶ 259 (emphasis omitted)).
  - Mukherjee: "We're almost done, and percentage will not give the right – so essentially everything whatever is committed has been done. The

institutionalization of activities, which are ongoing which will always continue. Right. So we are about to send out the letter with a request for re-inspection very soon." (AC at ¶ 260 (emphasis omitted)).

- Chakraborty: The remediation cost "is pretty much done. So far, we would have spent altogether around $36 million and I think it could be couple of million more in future." (AC at ¶ 261 (emphasis omitted)).
- Unidentified Defendant: "Progress on quality management processes [was] in line with expectations [and they] [s]ubstantially completed the commitments on the CAPAs." (AC at ¶ 262 (emphasis omitted)).

- Misstatement 18: During an October 25, 2016 earnings call concerning Q2 FY 2017, Defendant Mukherjee stated that investors "have done [their] part of it in terms of completing all the remediation activities," and that there was "[c]onsiderable progress in [their] remediation efforts." (AC at ¶¶ 263-64 (emphases omitted)).
- Misstatement 19: In a Form 9-K, issued October 25, 2016, Defendants stated:

> Co-chairman and CEO, G V Prasad said "All our major businesses have shown sequential improvement over the previous quarter with revenues growing by 11% and EBITDA by 61%. We have made considerable progress in our remediation efforts and continue to work on addressing the concerns of the regulators. Looking ahead we will continue to focus on launching new products in our generics business, improving productivity and strengthening our quality management systems."

(AC at ¶ 265 (emphasis omitted)).

- Misstatement 20: In a February 4, 2017 earnings call concerning Q3 FY 2017, Defendant Mukherjee stated:

> On the quality front as communicated earlier, our warning with the impacted sites are scheduled to get reaudited during

> the month of February and March. A substantial remediation work has been put in place from our side. Our application of corrective and preventive actions or CAPAs were not just site specific, but they were also network wide and incorporated third-party review and assessments. We believe we have prepared ourselves well for the audit. In the process of implementing the CAPAs, we have made significant progress in enhancing our quality systems and infilling the consumer quality and [continuous] improvement.

(AC at ¶ 266 (emphasis omitted)).

- Misstatement 21: During a November 9, 2015 conference call with Defendants Chakraborty, Reddy, and Mukherjee, Prasad made the following statements:

  - First statement:

    > The issues cited in the letter are GMP violations relating primarily to (a) documentation practices and control, (b) laboratory testing procedures, (c) incident investigation practices as well as (d) some standard operating procedures. At this time, we feel confident in the safety and efficacy of our products; however, we plan to do a comprehensive assessment of any risk to the quality of our products. This time, there is no directive from the FDA to stop the manufacturing activity or shipment of any products from these sites. As we respond to the agency, it is imperative for us to continue to strengthen our quality management systems and processes and enhance the infrastructure for training and development of our staff on the current cGMP practices. We have instituted corrective actions to address the 483 observations received earlier in each of these sites, which formed part of the updates shared with the agency.

    (AC at ¶ 278 (emphases omitted)).

  - Prasad also assured that Dr. Reddy's had taken steps to "derisk supply by transferring select products to alternate sites." (AC at ¶ 279 (emphasis omitted)).

- Finally, he stated, "[O]ur first priority today is products in the market, ensuring thereof they will meet all requirements and ensure there is no risk to entertain. That is our primary focus. . . . [O]ur first priority today is remediation, risk assessment and ensuring products are available what we're producing in the marketplace." (AC at ¶ 280 (emphases omitted)).

- Misstatement 22: During a February 9, 2016 conference call concerning "Q3 FY 2016," Defendant Mukherjee had the following exchange:

> Analyst: On the USFDA again, just trying and understanding after having assessed the warning letter and having consulted your third party, if there is any supply disruption in order to have third-party validation of goods or delay in shipments or because US run rate seem to be very much on track. Do you anticipate that happening or any disruption in supply or any delay in shipments?
>
> Mukherjee: As we had mentioned earlier that PSAI business had some impact of batch releases. We are closely in touch with the shortage loop if there is anything. But there is nothing major to be reported at this juncture from the existing set of products. For future – we do not want to comment, but currently there is nothing meaningful. PSAI part also is largely behind us, it is now back on track.
>
> Analyst: Just a clarification here on PSAI; the decline is largely due to one off impact, because warning letter you were clearly supplying and there is no issue as such for the upcoming quarters?
>
> Chakraborty: No, we mentioned that because of the remediation thing there were some delays in dispatches of API from these facilities.
>
> Analyst: But you are back on track?
>
> Chakraborty: Yes.

(AC at ¶ 281 (emphases omitted)).

On August 25, 2017, Plaintiff filed the original complaint alleging violations of Section 10(b) and Section 20(a) of the Securities Exchange Act of 1934 and SEC Rule 10b-5. (ECF No. 1). On November 21, 2017, the Court appointed Lead Plaintiff. (ECF No. 16). On February 16, 2018, Plaintiff filed a consolidated class action complaint, adding Defendants Dr. Reddy's USA and individual Defendants Reddy, and Mukherjee. (ECF No. 30). On March 5, 2018, Plaintiff filed the Amended Complaint. (ECF No. 35-36). The alleged class period is November 27, 2014 through September 15, 2017. (AC 18). Plaintiff purchased Dr. Reddy's securities between March 30, 2016 and April 6, 2016. (ECF No. 12-4).

LEGAL ANALYSIS

Standing

First, Defendants argue that Plaintiff cannot establish standing to bring this action because the pre-November 2015 alleged misstatements were corrected months prior to Plaintiff's first stock purchase on March 30, 2016, and the post-November 2015 alleged misstatements were made after Plaintiff's last stock purchase on April 6, 2016. In opposition, Plaintiff argues first that the pre-November 2015 statements were not fully corrected by disclosures made before Plaintiff's purchases because "the full truth" concerning the misstatements was not revealed until after Plaintiff purchased Dr. Reddy's securities. Second, Plaintiff contends that in similar actions, courts routinely have allowed lead plaintiffs to assert claims based on post-purchase statements if the lead plaintiff has standing for related claims based on pre-purchase misstatements. Finally, Plaintiff argues that any issues with standing would be better addressed at class certification.

The elements of Article III standing are well-established:

> [A] plaintiff must adequately establish: (1) an injury in fact (i.e., a "concrete and particularized" invasion of a legally protected interest"); (2) causation (i.e., a "fairly … trace[able]" connection between the alleged injury in fact and the alleged conduct of the defendant); and (3) redressability (i.e., it is "likely" and not "merely

> 'speculative" that the plaintiff's injury will be remedied by the relief plaintiff seeks in bringing suit).

Sprint Comm'cns Co. v. APCC Servs., Inc., 554 U.S. 269, 273-74 (2008) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). Generally, a "plaintiff may not maintain an action on behalf of a class against a specific defendant if the plaintiff is unable to assert an individual cause of action against that defendant." *Haas v. Pittsburgh Nat'l Bank*, 526 F.2d 1083, 1086 n.18 (3d Cir. 1975). "[N]amed representative plaintiffs initially need only establish that they individually have standing to bring their claims." *Ramirez v. STi Prepaid LLC*, 644 F. Supp. 2d 496, 504 (D.N.J. 2009). "If the named plaintiffs bringing a class action claims do not individually have standing to bring those claims, the case should be dismissed prior to the class certification process." *Id.* The reason for this is that "a plaintiff who lacks the personalized redressable injury required for standing to assert claims on his own behalf would also lack standing to assert similar claims on behalf of the class." *Id*. (quoting *Holmes v. Pension Plan of Bethlehem Streel Corp*., 213 F. 3d 124, 135 (3d Cir. 2000)).

"There is no private right of action under Rule 10b-5 for mere holders of securities." *Winer Family Tr. v. Queen*, 503 F.3d 319, 325 (3d Cir. 2007). The plaintiff "must be a purchaser or seller to pursue its Rule 10b-5 claims." *Id.*; *see also Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 755 (1975).

The standard as stated above, quickly dispenses with Plaintiff's argument that standing issues should be resolved at the class certification stage.

Pre-November 2015 Statements

Defendant contends Plaintiff cannot rely upon any statements made prior to the November 2015 Warning Letter because Plaintiff did not own shares in Dr. Reddy's until March 30, 2016. One case cited by Defendant found lack of standing in a similar action where a defendant corrected

prior disclosures in a press release before a lead plaintiff's securities purchase. "Generally, a plaintiff who did not reasonably rely on a misrepresentation or who suffered no loss because of a misrepresentation lacks standing to sue." *Id.* at 235. Accordingly, "a plaintiff who purchased after a corrective disclosure was made would have no standing, because relying on the earlier misrepresentation would no longer be reasonable in light of the new information; furthermore, the market is presumed to have processed the correction, which would be reflected in the stock price." *Id.* The court found the plaintiff may have grounds for suit for a later misstatement but, considering the intervening corrective disclosure, "they are not the same misrepresentation, or sufficiently similar, to constitute a single 'common scheme.'" *Id.*

The statements cited by Plaintiff concerning "the existence and extent of violations at Units V-VII" and "the existence and extent of violations at Dr. Reddy's other facilities" were clearly corrected by the Warning Letter. The Warning Letter provided a detailed description of the violations at United V, VI, and VII. It also addressed the totality of the violations in general terms: "Several violations are recurrent or represent long-standing failures to adequately resolve significant manufacturing quality problems. It is apparent that you have not implemented a robust quality system at your sites." (AC, Ex. 5, FDA Warning Letter).

The Warning Letter also addressed the alleged November 27, 2014 misstatement by Shilpi Lathia, a Dr. Reddy's spokesperson, "that the violations and corresponding remediation plans would have 'no implication on manufacturing,'" (*Id.* at ¶ 309), including by "strongly recommend[ing]" that Dr. Reddy's "evaluate global manufacturing operations to ensure compliance with CGMP regulations and requirements, comprehensively and immediately." (AC, Ex. 5, Warning Letter). The FDA also provided a contact number if Dr. Reddy's, "as a result of receiving [the] warning letter" decided to reduce the number of "finished products produced by

your manufacturing facility," (*Id.* at Ex. 5, Warning Letter). And finally, the FDA outlined potential steps to take as part of a "global corrective action and preventive action plan," including, "recalling product," "conducting additional testing," and "revising procedures," all of which could logically impact on manufacturing. (Warning Letter at 10-11).

Therefore, consistent with *City of Bristol Pension Fund*, Plaintiff here lacks standing to assert claims relating to alleged misstatements which were made prior to November 2015 – statements: 1 and 2 (both made on November 27, 2014), 3 (January 29, 2015), 4 (July 30, 2015), 5 (December 26, 2014), 6 (May 12, 2015), and 7 and 8 (both made in a June 17, 2015 form). (*See* AC at ¶¶ 214-237). The FDA Warning Letter sufficiently corrected the prior statements such that reliance on same would no longer be reasonable.

Post-November 2015 Statements

Defendants also challenge Plaintiff's standing to assert claims based on statements 9 through 12 and 16 through 20 because they "were allegedly made *after* Lead Plaintiff's last purchase of Dr. Reddy's stock" on April 6, 2016. (Defendant's Brief, ECF No. 47-2, at 12). Plaintiff urges this Court to apply an exception to the general rule that "[p]laintiffs cannot rely on statements made subsequent to their purchases in order to state a securities fraud claim." *In re Donald J. Trump Sec. Litig.*, 793 F. Supp. 543, 565 (D.N.J. 1992). Under the exception, a plaintiff may rely upon such statements if based on a "'common scheme to defraud' or 'interrelated misstatements and omissions.'" *Renz v. Schreiber*, 832 F. Supp. 766, 772 (D.N.J. 1993); *see also Hoexter v. Simmons*, 140 F.R.D. 416, 422 (D. Ariz. 1991).

However, recent case law leads the Court to conclude that such an exception is unavailable to Plaintiff. In *Winer Family Tr. v. Queen*, 503 F.3d 319, 325 (3d Cir. 2007) (emphasis added), the court affirmed dismissal of claims based on fraudulent conduct that occurred after the purchase of

shares without considering the exception, holding that the plaintiff "*only* has standing to assert claims based on activity *prior to* the date Winer purchased its stock." Another decision only a few years later reprised that holding: "As an individual, a lead plaintiff can *only* bring claims concerning alleged fraudulent activity occurring *before* its last sale or purchase." *In re NutriSystem, Inc. Sec. Litig.*, 653 F. Supp. 2d 563, 580 (E.D. Pa. 2009) (emphasis added); *see also In re Gen. Motors Class E Stock Buyout Sec. Litig.*, 694 F. Supp. 1119, 1126 (D. De. 1988) (dismissing because "[n]o reliance can be established for events occurring after the purchase of stock").

Therefore, Plaintiff may not assert claims arising out of alleged misstatements 9 and 10 (both made in a June 23, 2016 form); 11 (statements appearing on corporate website "at least since July 2016" (AC at ¶ 241)); 12 (June 17, 2016); 16 (May 12, 2016); 17 (July 26, 2016); 18 (October 25, 2016); 19 (October 25, 2016); and 20 (February 4, 2017). (AC at ¶¶ 238-247, 257-277). Each of these statements were made after April 6, 2016, the last day Plaintiff purchased shares.

Plaintiff does, however, have standing to pursue claims based on alleged misstatements 13 (November 6, 2015); 14 (November 9, 2015); 15 (February 9, 2016); 21 (November 9, 2015), and 22 (February 9, 2016). Each of these statements was made after the market learned of the Warning Letter on November 6, 2015, and prior to Plaintiff's purchases. As such, they could not have been corrected by the Warning Letter, and Plaintiff has a plausible claim that it relied upon them in connection with a transaction. Because Plaintiff has standing to pursue its claims arising out of those alleged misstatements, the complaint is not subject to dismissal on this ground.

Failure to State a Claim

Defendants' remaining arguments challenge the substantive viability of the complaint under Federal Rule of Civil Procedure 12(b)(6). The Court is required to accept as true all

allegations in the Complaint and all reasonable inferences that can be drawn therefrom, and to view them in the light most favorable to the non-moving party. *See Oshiver v. Levin, Fishbein, Sedran & Berman,* 38 F.3d 1380, 1384 (3d Cir. 1994). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 570 (2007)). While a court will accept well-pleaded allegations as true for the purposes of the motion, it will not accept bald assertions, unsupported conclusions, unwarranted inferences, or sweeping legal conclusions cast in the form of factual allegations. *Iqbal,* 556 U.S. at 678-79; *see also Morse v. Lower Merion Sch. Dist.,* 132 F.3d 902, 906 (3d Cir. 1997). A complaint should be dismissed only if the well-pleaded alleged facts, taken as true, fail to state a claim. *See In re Warfarin Sodium,* 214 F.3d 395, 397-98 (3d Cir. 2000).

"In alleging fraud or mistake, a party must state with particularly the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). "This stringent particularity requirement . . . applies to allegations of securities fraud." *In re Westinghouse Sec. Litig.*, 832 F. Supp. 948, 965 (W.D. Pa. 1993), *rev'd in part on other grounds*, 90 F.3d 696 (3d Cir. 1996).

Scienter Pleading

Defendant next contends the complaint should be dismiss because it does not adequately establish an inference of scienter for any defendant. "To Adequately allege a § 10(b) securities fraud claim, a plaintiff must plead '(1) a material misrepresentation or omission, (2) *scienter*, (3) a connection between the misrepresentation or omission and the purchase or sale of a security, (4) reliance upon the misrepresentation or omission, (5) economic loss, and (6) loss causation.'" *In re Hertz Global Holdings, Inc.*, 905 F.3d 106, 114 (3d Cir. 2018) (emphasis added) (quoting *City of*

Edinburgh Council v. Pfizer, Inc., 754 F.3d 159, 167 (3d Cir. 2014)).

To adequately plead scienter, "a plaintiff must 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *Id.* (quoting 15 U.S.C. § 78u-4(b)(2)(A)). In considering a motion to dismiss, the inquiry "is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation scrutinized in isolation, meets that standard." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322-23 (2007). The inference of scienter alleged "must be more than merely plausible or reasonable – it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *City of Edinburgh Council*, 754 F.3d at 176 (quoting *Tellabs, Inc.*, 551 U.S. at 314). Plaintiffs allege three bases to support an inference of scienter: (1) direct contradictions of the truth by Defendants; (2) misstatements by Defendants about a core Dr. Reddy's operation; and (3) allegations by a confidential witness.

Direct Contradictions of the Truth

Pointing to the alleged misstatements themselves, Plaintiff argues that "[t]he striking contrast between the true state of affairs at Defendants' manufacturing facilities" and Defendants' statements creates "a strong inference of scienter." (Plaintiff's Brief, at 17). Oftentimes "the most powerful evidence of scienter is the content and context of [the] statements themselves." *Inst. Investors Grp. v. Avaya, Inc.*, 564 F.3d 242, 269 (3d Cir. 2009). Plaintiff points to discrepancies between Defendants' statements to analysts and their statements to the FDA, and Defendants' apparent ignorance of non-compliance despite the Warning Letter and Form 483s from the FDA.

Plaintiff has pointed to statements by Defendants that directly contradicted the truth about the company's actions at the time. For example, during conference calls with investors on November 9, 2015 and February 9, 2016, Defendants Prasad, Mukherjee, and Chakraborty made

statements indicating: Dr. Reddy's planned to comprehensively assess risks; Dr. Reddy's had begun to implement a comprehensive and preventative action plan; and the company's pharmaceutical services and active ingredient business was "back on track." According to the complaint, at the time of these statements, "Defendants had no intention of adequately addressing the violations of cGMP detailed in the Warning Letter, because they knowingly failed to implement the FDA's corrective plan of action." (AC, at ¶ 252). That allegation is bolstered by additional allegations that "upon reinspection of their Units V, VI, and VII facilities, the FDA determined that serious cGMP violations still existed and in fact 'found that numerous items had not been corrected,'" (AC at ¶ 255), and that Defendants knew or should have known that their third-party consulting firm retained to provide compliance and remediation support in implementing the CAPA plan "caused substantial delays in approving products for dispatch," (*Id.* at ¶ 282).

In addition, Plaintiff identifies other statements of Defendants. During a July 30, 2015 conference call Defendant Mukherjee claimed that the problems the FDA raised in November 2014 were a "one site specific issue"; a claim that contradicted two prior undisclosed FDA Form 483 observations regarding two other facilities. (AC at ¶ 228-229). Later, Defendant Mukherjee stated in a May 12, 2016 conference call that "most" of the company's "commitments to the agency will be over by the end of the year," (AC at ¶ 257), and in a February 4, 2017 conference call that the company had "made significant progress in enhancing our quality systems," (*Id.* at ¶ 266). These statements were in stark contrast to the allegation that the FDA subsequently discovered "that serious cGMP violations still existed and in fact . . . that numerous items had not been corrected." (*Id.* at ¶ 267). Although some of these statements were made outside the purchase period, they are nonetheless relevant "as circumstantial evidence of fraudulent intent." *Renz*, 832

F. Supp. at 774.

Defendants' alleged failure to investigate FDA warnings weighs further in favor of finding scienter and falsity. "[W]hen the FDA tells a company about a problem with a product, and the company nonetheless continues to make confident predictions about a product, courts have inferred scienter and falsity." *Frater v. Hemispherx Biopharma, Inc.*, 996 F. Supp. 2d 335, 350 (E.D. Pa. 2014) (quoting *In re MannKind Sec. Actions*, 835 F. Supp. 2d 797, 811 (C.D. Cal. 2011)). Indeed, the FDA Warning Letter itself stated, "You are responsible for determining the causes of these violations and deviations, for preventing their recurrence, and for preventing other violations and deviations." (AC at Ex. 5, Warning Letter at 9). The allegations that Defendants' statements were false at the time they were made is sufficient evidence of scienter for this analysis.

Misstatements About Core Operations

Plaintiff also argues that Defendants' misstatements about Dr. Reddy's compliance with FDA regulations concerned a core operation, giving rise to a strong inference of scienter. The Third Circuit has recognized "a core operations doctrine" in assessing scienter. *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 246 (3d Cir. 2013) (quoting *Avaya*, 564 F.3d at 271-72). More specifically, "under the core operations doctrine, misstatements and omissions made on 'core matters of central importance' to the company and its high-level executives give[] rise to an inference of scienter when taken together with additional allegations connecting the executives' positions to their knowledge." *In re Urban Outfitters, Inc. Sec. Litig.*, 103 F. Supp. 3d 635, 653-54 (E.D. Pa. 2015).

One court has held, "Given that [the brand, which comprised 44% of all sales,] is a core operation of [the defendant], combined with plaintiff's allegations and circumstantial evidence . . . plaintiff's allegations are sufficient to give rise to the strong inference that defendants were, at

minimum, reckless in their statements." *In re Urban Outfitters*, 103 F. Supp. 3d at 654. Another court has found a "logical, and strong, inference that the defendants were aware of the alleged severe and pervasive problems" in light of "the importance of manufacturing and quality control . . . and the fact that both areas of operation had been flagged by the FDA." *Mulligan v. Impax Labs., Inc.*, 36 F. Supp. 3d 942, 970 (N.D. Cal. 2014).

According to the allegations, as a pharmaceutical company, a core aspect of Dr. Reddy's business "is ensuring compliance with safety and manufacturing quality standards for each jurisdiction in which they sell products." (AC at ¶ 356). The FDA Warning Letter cautioned that absent corrective action, the "FDA may withhold approval of any new applications or supplements listing [Dr. Reddy's] as a drug product or API manufacturer," and that the "FDA may also refuse admission of articles into the United States." (*Id.* at Ex. 5, Warning Letter at 10). As United States sales comprised nearly half of Dr. Reddy's revenue, (AC at ¶¶ 84, 66-72), an interruption in those sales would constitute a disruption in the company's core operations. It can therefore be inferred at this stage of the litigation that Defendants were aware of the threat to operations posed by the company's noncompliance with cGMP.

Statements by a Confidential Witness

"[A] plaintiff in securities fraud actions can support a complaint by reliance on information attributed to confidential sources" but only "in two situations: (1) if the complaint sets forth other factual allegations, such as documentary evidence, which are sufficient alone to support a fraud allegation, or (2) when the confidential sources are described in the complaint with sufficient particularity to support the probability that a person in the position occupied by the confidential source would possess the information alleged." *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 290 (D.N.J. 2007); *see also Nat'l Junior Baseball League v. Pharmanet Dev. Grp., Inc.*, 720 F.

Supp. 2d 517, 538-39 (D.N.J. 2010).

In this case, the one confidential witness serves only to bolster the allegations which are otherwise pled with sufficient particularity. The allegations are not solely or substantially dependent on CW 1's statements. This case is therefore distinguishable from *Institutional Investors Group v. Avaya, Inc.*, 564 F.3d 242, 260 (3d Cir. 2009), where the plaintiffs' "allegations primarily relied on the representations of [six] confidential witnesses." Therefore, the information provided by the confidential witness here is sufficient to support an inference of scienter. The Court need not consider whether CW 1 provided information with sufficient particularity because the totality of the allegations in the complaint provide sufficient particularity.

Overall Indicia of Scienter

Overall, the totality of the direct contradictions of the truth, statements about core operations, information provided by Plaintiff's confidential witness, and additional allegations support a strong inference of scienter. Plaintiff alleges that the company emphasized its "rigorously implemented Quality Management System," (AC at ¶ 82), had received prior warning letters and Form 483s, (AC at ¶¶ 13, 16, 120, 140, 144, 376-378), and Defendants operated "an undisclosed quality control laboratory that selectively reported passing results," (AC, at ¶ 126).

These allegations serve to further bolster Plaintiff's arguments. "In sum, the reviewing court must ask: When the allegations are accepted as true collectively, would a reasonable person deem the inference of scienter at least as strong as any opposing inference?" *See Tellabs, Inc.*, 551 U.S. at 326. Plaintiff has sufficiently alleged scienter, in considering the totality of the allegations.

Actionability of the Misstatements

Corporate Puffery

Defendants next contend that statements 13 and 14 are too vague to be actionable and therefore amount to no more than corporate puffery. "[V]ague and general statements of optimism 'constitute no more than "puffery" and are understood by reasonable investors as such.'" *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 538 (3d Cir. 1999) (quoting *Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997)). "Such statements, even if arguably misleading, do not give rise to a federal securities claim because they are not material: there is no 'substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the "total mix" of information available.'" *Advanta Corp.*, 180 F.3d at 538 (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 449 (1976)). For example, court has declined to find statements about a company's "dedication to disciplined pricing" to be actionable. *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 284 (3d Cir. 2010).

Statements 13 and 14 were not mere puffery because they addressed steps the company had purportedly taken to comply with the cGMP, which the FDA had found that the company violated. Statements about whether the company has taken steps to bring itself into compliance with this standard are "determinate" and "verifiable" and thus "not mere puffery." *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 135 S.Ct. 1318, 1326 (2015). The Court also notes a similar case where the plaintiffs alleged that the defendants "took corrective action to address the company's problems," which the court found posed a question of fact. *Wilkof v. Caraco Pharm. Laboratories, Ltd.*, No. 09-CV-12830, 2010 WL 4184465 at 4 (E.D. Mich. Oct. 21, 2010). That case also held that "whether [the defendant] was compliant with cGMP regulations is an issue subject to objective verification." The Court declines to dismiss the claims relating to statements

13 and 14 as mere puffery.[1]

PSLRA Safe Harbor

Defendants next argue that statements 13, 14, and 21 are not actionable because they are protected by the PSLRA safe harbor provision, which provides that statements are not actionable if they are "forward-looking as defined by the statute provided that they are (1) identified as such, and accompanied by meaningful cautionary statements; or (2) immaterial; or (3) made without actual knowledge that the statement was false or misleading." *Aetna, Inc.*, 617 F.3d 272, 278-79 (3d Cir. 2010). "A mixed present/future statement is not entitled to the safe harbor with respect to the part of the statement that refers to the present." *Inst. Investors Grp. v. Avaya, Inc.*, 564 F.3d 242, 255 (3d Cir. 2009) (quoting *Makor Issues & Rights, Ltd. v. Tellabs, Inc.*, 513 F.3d 702, 705 (7th Cir. 2008)).

Certain statements made on November 6 and 9, 2015, (statements 13, 14, and 21) were not forward looking and thus were not covered by the safe harbor provision. In a November 6, 2015 press release, Defendants stated, "We *have embarked* on an initiative to revamp our quality systems and processes, as an organization-wide priority" (*See* AC at ¶ 248 (emphasis added)). In a November 9, 2015 conference call Defendants stated, "We *have embarked* on an initiative to revamp our quality systems and processes, as an organization-wide priority" (AC at ¶ 250 (emphasis added)). In the same conference call, a claim was made that Defendants *had* "*instituted* corrective actions to address the 483 observations received earlier in each of these sites" (AC at ¶ 278 (emphasis added)). These statements are not within the safe harbor provision merely because Defendants made other related statements that *were* forward looking: "The mere fact that a

[1] Relatedly, the statements cited in the complaint are not mere statements of opinion. Statement 21, the only statement over which Plaintiff has standing that is challenged as an opinion, included factual claims; specifically, that Dr. Reddy's "instituted corrective actions to address the 483 observations received earlier in each of these sites." (AC at ¶ 278).

statement contains some reference to a projection of future events cannot sensibly bring the statement within the safe harbor if the allegation of falsehood relates to non-forward-looking aspects of the statement." *In re Stone & Webster, Inc., Sec. Litig.*, 414 F.3d 187, 213 (1st Cir. 2005) The Court therefore need not address the remaining safe harbor criteria.

Section 20(a) Claim

Defendants seek dismissal of Plaintiff's claims against individual Defendants (Prasad, Chakraborty, Mukherjee, and Reddy) and against Dr. Reddy's, USA, for failure to adequately allege joint and several liability. According to section 20(a) of the Exchange Act:

> Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a). To set forth a claim for joint and several liability under section 20(a), a plaintiff must allege that defendants "exercise[] control over a 'controlled person' who violates Section 10(b)." *Carmack v. Amaya, Inc.*, 258 F. Supp. 3d 454, 466 (D.N.J. 2017). "The three elements of a Section 20(a), or "control person" claim are as follows: (1) the defendant controlled another person or entity; (2) the controlled person or entity committed a primary violation of the securities laws; and (3) the defendant was a culpable participant in the fraud." *Id.* (citing *In re Suprema Specialties, Inc., Sec. Litig.*, 438 F.3d 256, 286 (3d Cir. 2006)).

As to the joint and several liability allegations against Dr. Reddy's, USA, the complaint alleges that Dr. Reddy's, USA, is the registered agent of Dr. Reddy's and its wholly owned United States subsidiary. (AC at ¶ 51). Plaintiff also alleges that Dr. Reddy's, USA, "acted as a controlling person of the company," (AC at ¶ 448), and that there was "a significant degree of overlap between directors" at both companies. (Plaintiff's Brief, ECF No. 48 at 44). The Court finds these

allegations sufficient for the complaint to survive this motion and shall permit discovery as to, among other topics, Dr. Reddy's USA's liability.

With regard to the individual Defendants, Plaintiff alleges each held high positions at Dr. Reddy's – CEO, CFO, COO, and co-chairman. According to the complaint, Prasad, Chakraborty, and Mukherjee signed germane documents and participated in earnings calls. (AC at ¶ 52-57). Reddy also signed germane documents and was "responsible in part for the Annual Reports." (*Id.* at ¶ 58). In addition, the Amended Complaint details the alleged misstatements of each individual Defendant.[2] Plaintiff has adequately alleged that the individual Defendants were controlling persons; "an intensely factual question." *Sec. Exch. Comm'n v. Todd*, 642 F.3d 1207, 1223 (9th Cir. 2011). The Court therefore declines to dismiss Plaintiff's complaint against either the individual Defendants or Dr. Reddy's USA.

ORDER

This matter comes before the Court on a motion filed by Defendants to dismiss Plaintiff's Amended Consolidated Class Action Complaint. The Court has considered the papers submitted in support of and in opposition to the motion and the exhibits attached thereto and held oral argument on the matter on August 8, 2018. Accordingly, for the reasons set forth in the written memorandum that accompanies this order, and for good cause shown;

IT IS on this 20th day of March, 2019,

ORDERED that Defendants' motion to dismiss, (ECF No. 47), is granted in part and denied in part; and it is further

ORDERED that Plaintiffs lack standing to assert claims relating to the following alleged

[2] *See* AC at ¶¶ 201, 202, 207, 225, 227, 228, 229, 251, 257, 258, 260, 263, 266, 278, 280, 281, 317 (Mukherjee); ¶¶ 198, 199, 200, 232, 238, 248, 249, 250, 278, 279, 280, 298, 404 (Prasad); ¶¶ 208, 232, 238, 259, 261, 278, 281, 292, 311, 317, 369, 402, 405 (Chakraborty); ¶¶ 237, 244, 278 (Reddy).

misstatements:

- Misstatement 1: Amended Complaint, ¶¶ 214-15
- Misstatement 2: Amended Complaint, ¶ 216
- Misstatement 3: Amended Complaint, ¶ 225
- Misstatement 4: Amended Complaint, ¶ 228
- Misstatement 5: Amended Complaint, ¶ 230.
- Misstatement 6: Amended Complaint, ¶ 231
- Misstatement 7: Amended Complaint, ¶ 232
- Misstatement 8: Amended Complaint, ¶ 233
- Misstatement 9: Amended Complaint, ¶ 238
- Misstatement 10: Amended Complaint ¶ 239
- Misstatement 11: Amended Complaint, ¶¶ 240-43
- Misstatement 12: Amended Complaint, ¶ 244
- Misstatement 16: Amended Complaint, ¶ 257
- Misstatement 17: Amended Complaint, ¶¶ 258-62
- Misstatement 18: Amended Complaint, ¶¶ 263-64
- Misstatement 19: Amended Complaint, ¶ 265
- Misstatement 20: Amended Complaint, ¶ 266; and it is further

ORDERED that Plaintiffs do have standing to assert claims relating to the following alleged misstatements:

- Misstatement 13: Amended Complaint, ¶ 248
- Misstatement 14: Amended Complaint, ¶ 249
- Misstatement 15: Amended Complaint, ¶ 251
- Misstatement 21: Amended Complaint, ¶ 266
- Misstatement 22: Amended Complaint, ¶ 280; and it is further

ORDERED that in all other respects, Defendants' motion is denied.

s/Peter G. Sheridan
PETER G. SHERIDAN, U.S.D.J.

March 20, 2019